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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,667	01/14/2004	Anthony John Kinney	BB1071 US DIV2	7292

23906 7590 07/09/2009
E I DU PONT DE NEMOURS AND COMPANY
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4417 LANCASTER PIKE
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EXAMINER

KUMAR, VINOD

ART UNIT	PAPER NUMBER
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1638

NOTIFICATION DATE	DELIVERY MODE
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07/09/2009

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/757,667
Filing Date: January 14, 2004
Appellant(s): KINNEY ET AL.

Lynne M. Christenbury
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 3/17/2009 and 4/29/2009 appealing from the Office action mailed 10/15/2008.

1. Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

2. Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

3. Status of Claims

The statement of the status of the claims contained in the brief is correct.

4. Status of Amendments

The appellant's statement of the status of amendments contained in the brief is correct. The appellant's statement that a response after Final was filed on 12/18/2008 and was entered on 02/09/2009 for purpose of this appeal is correct.

5. Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

6. Grounds of Rejection to be Reviewed on Appeal

Appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

7. Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

8. Evidence Relied Upon

Trueblood et al. (U.S. Patent No. 4,267,118, Issued May 12, 1981).

Staswick et al. (Archives of Biochemistry and Biophysics, 223:1-8, 1983).

9. Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102 & 103

A. Claims 22-24 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Trueblood et al. (US Patent No. 4,267,118, issued on May 12, 1981).

Claims are broadly drawn to food comprising a soy protein product prepared from transgenic soybean seeds having a reduced quantity of soybean seed storage protein and prepared by a method comprising: (a) constructing a chimeric gene comprising: (i) a nucleic acid fragment comprising a promoter that is functional in the cells of soybean seeds; (ii) a nucleic acid fragment encoding all or a portion of a soybean seed storage protein placed in sense or antisense orientation relative to the promoter of (i) wherein said soybean seed storage protein is selected from the group consisting of glycinin and 13-conglycinin; and (iii) a transcriptional termination region; (b) creating a transgenic soybean cell by introducing into a soybean cell the chimeric gene of (a); and (c) growing the transgenic soybean cells of step (b) which express the chimeric gene of step (a) wherein the quantity of one or more members of a class of soybean seed storage protein subunits is reduced when compared to soybean seeds not comprising the chimeric gene of step (a), and wherein the class of soybean seed storage protein subunits is selected from the group consisting of: glycinin and 13-conglycinin or food comprising a

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soy protein prepared from transgenic soybean seeds prepared by a method for simultaneously reducing the expression of two soybean genes comprising: (a) constructing a chimeric gene comprising: (i) a nucleic acid fragment comprising a promoter region from a soybean seed storage protein gene; and (ii) a nucleic acid fragment encoding all or a portion of a soybean protein that is not the soybean seed storage protein of (i) wherein said soybean seed storage protein is selected from the group consisting of glycinin and 13-conglycinin, said nucleic acid fragment placed in a sense or antisense orientation relative to the promoter of (i), and (iii) a transcriptional termination region; (b) creating a transgenic soybean seed by introducing into a soybean seed the chimeric gene of (a); and (c) growing the transgenic soybean seeds of step (b) which express the chimeric gene of step (a); wherein the quantity of one or more members of a class of soybean seed storage protein subunits and the quantity of the protein encoded by the nucleic acid fragment of (a)(ii) is reduced when compared to soybeans seeds not comprising the chimeric gene of step (a), and wherein the class of soybean seed storage protein subunits is selected from the group consisting of glycinin and β -conglycinin, or food comprising a soy protein prepared from transgenic soybean seeds obtained from a soybean plant transformed at a single locus in its genome with a chimeric gene comprising at least a portion of a glycinin or a β -conglycinin gene for reducing the amount of at least one soybean seed storage protein in soybean seeds wherein the seed storage protein is selected from the group consisting of glycinin and 13-conglycinin, when compared to seeds obtained from a soybean plant not comprising the chimeric gene in its genome.

Trueblood et al. disclose vegetable oil (food) prepared from soybean seeds. See abstract, claims 1-16 and columns 1-5. The food taught in the reference was not made using the same method as the instantly claimed food. However, the instantly claimed food has the same structural limitations as that taught by the reference. Soybean oil as a food obtained from the claimed method appears to be identical to the soybean oil of the prior art. See *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) which teaches that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."

The instantly claimed food reads on soybean oil which would inherently comprise oilbody proteins (e.g. oleosins, a soybean seed protein) including other soybean seed protein contaminants. It is important to note that since soybean oil does not contain seed storage protein subunits like, glycinin or β -conglycinin, one of skilled in the art would not be able to distinguish the structure of Trueblood et al. oil from the oil prepared from the instantly claimed product by process methods. Thus, one of skilled in the art would not be able to see the reduced quantity of glycinin and/or β -conglycinin in Trueblood et al. soybean oil or the oil prepared from the instant soybean transgenic seeds. Furthermore, since soybean oil does not contain genetic material (DNA or RNA), one of skill in the art would not be able to distinguish the structure of Trueblood et al. oil from the oil prepared from the instant soybean transgenic seeds. In view of this, the claim limitations directed to

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reducing soybean seed storage protein subunit glycinin and β -conglycinin in a transgenic soybean seed are not important and carry no structural weight.

(B) Claims 22-24 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Staswick et al. (Archives of Biochemistry and Biophysics, 223:1-8, 1983).

Claims are broadly drawn to food comprising a soy protein product prepared from transgenic soybean seeds having a reduced quantity of soybean seed storage protein and prepared by a method comprising: (a) constructing a chimeric gene comprising: (i) a nucleic acid fragment comprising a promoter that is functional in the cells of soybean seeds; (ii) a nucleic acid fragment encoding all or a portion of a soybean seed storage protein placed in sense or antisense orientation relative to the promoter of (i) wherein said soybean seed storage protein is selected from the group consisting of glycinin and β -conglycinin; and (iii) a transcriptional termination region; (b) creating a transgenic soybean cell by introducing into a soybean cell the chimeric gene of (a); and (c) growing the transgenic soybean cells of step (b) which express the chimeric gene of step (a) wherein the quantity of one or more members of a class of soybean seed storage protein subunits is reduced when compared to soybean seeds not comprising the chimeric gene of step (a), and wherein the class of soybean seed storage protein subunits is selected from the group consisting of: glycinin and β -conglycinin or food comprising a soy protein prepared from transgenic soybean seeds prepared by a method for simultaneously reducing the expression of two soybean genes comprising: (a) constructing a chimeric gene comprising: (i) a nucleic acid fragment comprising a promoter region from

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a soybean seed storage protein gene; and (ii) a nucleic acid fragment encoding all or a portion of a soybean protein that is not the soybean seed storage protein of (i) wherein said soybean seed storage protein is selected from the group consisting of glycinin and β -conglycinin, said nucleic acid fragment placed in a sense or antisense orientation relative to the promoter of (i), and (iii) a transcriptional termination region; (b) creating a transgenic soybean seed by introducing into a soybean seed the chimeric gene of (a); and (c) growing the transgenic soybean seeds of step (b) which express the chimeric gene of step (a); wherein the quantity of one or more members of a class of soybean seed storage protein subunits and the quantity of the protein encoded by the nucleic acid fragment of (a)(ii) is reduced when compared to soybeans seeds not comprising the chimeric gene of step (a), and wherein the class of soybean seed storage protein subunits is selected from the group consisting of glycinin and β -conglycinin, or food comprising a soy protein prepared from transgenic soybean seeds obtained from a soybean plant transformed at a single locus in its genome with a chimeric gene comprising at least a portion of a glycinin or a β -conglycinin gene for reducing the amount of at least one soybean seed storage protein in soybean seeds wherein the seed storage protein is selected from the group consisting of glycinin and β -conglycinin, when compared to seeds obtained from a soybean plant not comprising the chimeric gene in its genome.

Staswick et al. disclose soybean seeds having reduced levels of glycinin. The soybean seed storage proteins with reduced levels of glycinin would inherently constitute food. See in particular, page 1, abstract, introduction; page 2; left column. The soybean seed storage proteins with reduced glycinin levels disclosed in the reference was not made

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using the same method as the instantly claimed food. However, the instantly claimed food has the same structural limitations as that taught by the reference. Soybean seed storage proteins with reduced glycinin levels as a food obtained from the claimed method appears to be identical to the soybean seed storage proteins with reduced glycinin levels of the prior art. See *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) which teaches that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."

It is important to note that since Staswick et al. soybean seeds have reduced quantity of glycinin, one of skill in the art would not be able to distinguish the structure of Staswick et al. the food (seed storage proteins) from the transgenic soybean seed storage protein food prepared from the instantly claimed product by process methods. Furthermore, since soybean seed storage proteins do not contain genetic material (DNA or RNA), one of skill in the art would not be able to distinguish the structure of Staswick et al. food (seed storage proteins) from the seed storage protein food prepared from the instant soybean transgenic seeds. Thus, soybean seed storage proteins with reduced glycinin levels as a food obtained from the claimed method appears to be structurally identical to the soybean seed storage proteins with reduced glycinin levels of Staswick et al.

(10) Response to Arguments

(a) Claims 22-24 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Trueblood et al. (US Patent No.

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4,267,118, issued on May 12, 1981). The rejection is maintained for the reasons of record. Appellant traverses the rejection.

Appellant traverses primarily that Trueblood et al. concerns a process for treating crude soybean oil to make it a food or commercial grade quality. Appellant further argues that Trueblood et al. food grade quality oil has a protein content of less than 0.1%. Applicant further argues that by definition, the lowest level of soy protein in a soy protein product is about 40% protein. Appellant cites Appendix C and Appendix D (filed with appeal brief) to support the argument that a soy protein product such as soy flour would have at least 40% protein (response, brief on appeal, page 6, line 1 through line 13 of page 7).

Appellant's traversals have been carefully considered but are unpersuasive for the following reasons:

Appellant's attention is drawn to MPEP 2106 [R-6] II C, which states:

"USPTO personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. In re Morris, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Limitations appearing in the specification but not recited in the claim should not be read into the claim. E-Pass Techs., Inc. v. 3Com Corp., 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003) (claims must be interpreted "in view of the specification" without importing limitations from the specification into the claims unnecessarily). In re Prater, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969). See also In re Zletz, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) ("During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow.... The reason is simply that during patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed.... An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.")"

In the instant case, "food" as instantly claimed reads on soybean oil which inherently comprises oilbody proteins (e.g. oleosin, a soy protein) including other soy

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protein contaminants. It is important to note that soybean oil constitutes a "food" (cooking oil) that is made up of oilbodies comprising soybean oil. The oilbody is itself composed of oilbody proteins, such as oleosin which is a soy protein.

In response to applicant's argument that the reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., soy protein product having at least about 40% protein) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).
57 (Fed. Cir. 1993).

The instantly claimed food has the same structural limitations as that taught by the reference. Soybean oil as a food obtained from the claimed method appears to be identical to the soybean oil of the prior art which inherently comprises oleosins (same as soy protein). See *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) which teaches that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."

(b) Claims 22-24 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Staswick et al. (Archives of Biochemistry and Biophysics, 223:1-8, 1983). The rejection is maintained for the reasons of record. Appellant traverses the rejection.

Appellant traverses primarily that Staswick et al. are concerned with improving the nutritional quality of soybean seed protein by altering glycinin subunit composition. Appellant further argues that the cultivar used in Staswick et al. does not appear to be transgenic, whereas, the instant invention concerns food comprising a soy protein product prepared from transgenic soybean seeds having a reduced quantity of soybean seed storage protein. Appellant further argues that a chimeric gene recited in the claims comprises heterogenous regulatory and coding sequences not found in nature, accordingly food of the instant invention comprising a soy protein product as recited in claims would be distinguishable by the presence of the chimeric gene used to create the transgenic soybean plant producing the seeds from the soy protein products that were obtained (response, brief on appeal, page 7, line 18 through line 21 of page 8).

Appellant's traversals have been carefully considered but are unpersuasive for the following reasons:

Appellant's attention is drawn to MPEP 2106 [R-6] II C, which states:

"USPTO personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. In re Morris, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Limitations appearing in the specification but not recited in the claim should not be read into the claim. E-Pass Techs., Inc. v. 3Com Corp., 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003) (claims must be interpreted "in view of the specification" without importing limitations from the specification into the claims unnecessarily). In re Prater, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969). See also In re Zletz, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) ("During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow.... The reason is simply that during patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed.... An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.")"

In the instant case, “food” as instantly claimed reads on any soy protein derived from soybean seeds. The instantly claimed “food” reads on Staswick et al. soybean seed proteins having reduced levels of glycinin. The soybean seed storage proteins with reduced levels of glycinin reads on instantly claimed food prepared from soybean seeds. See in particular, page 1, abstract, introduction; page 2; left column.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., soy protein products as claimed contains chimeric construct) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).
57 (Fed. Cir. 1993).

The soybean seed storage proteins with reduced glycinin levels disclosed in the reference were not made using the same method as the instantly claimed food. However, the instantly claimed food has the same structural limitations as that taught by the reference. Soybean seed storage proteins with reduced glycinin levels as a food obtained from the claimed method appears to be identical to the soybean seed storage proteins with reduced glycinin levels of the prior art. See *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) which teaches that “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious a product of the

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prior art, the claim is unpatentable even though the prior product was made by a different process."

11. Related Proceedings Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejection should be sustained.

Respectfully submitted,

/Vinod Kumar/
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